Human Subject Protection Program (HSPP) Process Information For USD (Personnel &Readiness) Institutions

The protocol review and approval process varies depending on what institution(s) has primary responsibility for the conduct of the research. There are four primary review and approval processes:

1. The USD(P&R) institution is conducting the research and is primarily responsible for the research. If another institution(s) is involved, it is typically in a support role.
2. The USD(P&R) institution provides a supporting role for the research, but the research is being conducted by a contract organization or some other entity through a business relationship or it is conducted off-site.
3. The USD(P&R) institution is collaborating with another institution(s) and both institutions have equal responsibility for the research.
4. The USD(P&R) institution is engaged in the research solely because it is providing identifiable data to another institution for research purposes.

Process 1: The USD(P&R) institution is conducting the research and primarily responsible for the research. If another institution(s) is involved, it is typically in a support role.

Examples: Research conducted at USUHS by USUHS faculty and students; survey conducted by DMDC with administrative support from a contract organization.

Requirements: The P&R institution must have an Assurance. If the other institution(s) provides more than administrative services or funding, it needs an Assurance. If the supporting institution is engaged in the research and has an Assurance, then the institutions should have an IRB Authorization Agreement in which the P&R institution's IRB is designated as the primary IRB.

1. The Principal Investigator (PI) develops the protocol.

2. The PI submits the protocol to an Exempt Determination Official (EDO). This can be done directly (e.g., DMDC, DEOMI, PERSEREC), through the Information Management Control Officer (IMCO) (e.g., TMA, MPP, CPP), or through the IRB office (USUHS).

3. EDO determines if the protocol a) is not human subjects research, b) is human subjects research, but exempt, or c) is human subjects research that is not exempt (i.e., requires either expedited or full-board review).

   If a) the EDO informs PI and may decide to document the decision.

   If b) the EDO informs PI and documents the decision.

   If c) the EDO requests IRB review from the IRB of record for that institution.

4. P&R IRB review process (see Appendix A for more detail).

5. Approved protocol with documentation is forwarded to other review/oversight offices as needed (e.g., Privacy Office, WHS Survey License, DoD Clearance Officer, etc.).

Process 2: The USD(P&R) institution provides a supporting role for the research, but the research is being conducted by a contract organization or some other entity through a business relationship or it is conducted off-site.

Examples: TMA or MPP are engaged in the research either because they help design the study or they provide identifiable, private information to the researchers; however, the contract organization conducts the research. USUHS student or P&R employee conducts research at an external site.

Requirements: All engaged institutions must have an Assurance. An IRB Authorization agreement designates the contract organization's or external site's IRB as the primary IRB.

1. The Principal Investigator (PI) develops the protocol.

2. The PI submits the protocol to the contracted organization's or external site's IRB of record.

3. The IRB a) determines the protocol is not human subjects research, b) determines the protocol is human subjects research, but exempt, c) conducts an expedited review, or d) conducts a full-board review.

4. The PI and/or Contracting Officer submit the IRB approved or exempted protocol and IRB documentation to the Exempt Determination Official (EDO). This can be done directly (e.g., DMDC, DEOMI, PERSEREC), through the Information Management Control Officer (IMCO) (e.g., TMA, MPP, CPP), or through the IRB office (USUHS).

   If 3a or 3b) the EDO reviews the IRB decision and verifies compliance with DoD specific requirements. If b, EDO documents the decision.

   If 3c) the EDO reviews and forwards to Component Designated Oversight Office (CDOO) or (USUHS only) IRB chair with a recommendation for concurrence. Decision is documented.

   If 3d) the EDO forwards to their institution's IRB of record, through CDOO or (USUHS only) IRB chair, with a recommendation for concurrence. Note: The protocol must be submitted to the institution's IRB of record in the format required by that IRB.

5. Approved protocol is forwarded to other review/oversight offices as needed (e.g., Privacy Office, WHS Survey License, etc.).

Process 3: The USD(P&R) institution is collaborating with another institution(s) and both institutions have equal responsibility for the research.

Examples: Project in which DMDC researchers and University based researchers are collaborating and there may be no business relationship between the institutions, or .

Requirements: All institutions must have an Assurance. It may be possible to enter into an IRB Authorization Agreement; however, it is unlikely that the institutions involved

will agree under these conditions. Note: The lack of business relationship means that there will be stringent Privacy Act restrictions on data sharing.

1. The Principal Investigators develop the protocol and submit it for review to both institutions. P&R institutions follow process 1 above.

Process 4: The USD(P&R) institution is engaged in the research solely because it is providing identifiable data to another institution for research purposes.

Examples: Researchers contact DMDC or TMA Privacy Office for identifiable, private information for research purposes.

Requirements: The requesting institution and the P&R institution must have Assurances. Primary considerations are Privacy Act and for Protected Health Information (PHI), the Privacy Rule authorized by the Health Insurance Portability and Accountability Act.

1. The requestor develops the protocol and submits it for review to his/her IRB for review and approval.
2. The IRB a) determines the protocol is not human subjects research, b) determines the protocol is human subjects research, but exempt, c) conducts an expedited review, or d) conducts a full-board review
3. Requestor submits IRB approved protocol and approval or exemption letter with his/her Data Use Agreement request.
4. The data holder/authorizer forwards the approved protocol to the EDO.

   If 2a or 2b) the EDO reviews the IRB decision and verifies compliance with DoD specific requirements. If b, EDO documents the decision. EDO informs data holder/authorizer.

   If 2c) the EDO reviews and forwards for headquarters level (or secondary review) to Component Designated Oversight Office (CDOO) or (USUHS only) IRB chair with a recommendation for concurrence. Decision is documented and data holder/authorizer is informed.

   If 2d) the EDO forwards to their institution's IRB of record, through CDOO or (USUHS only) IRB chair, with a recommendation for concurrence. Note: The protocol must be submitted to the institution's IRB of record in the format required by that IRB. The data holder/authorizer is informed of IRB decision.

Appendix A: P&R IRB Review Processes

USUHS IRB

EDO recommends either expedited or full-board review.

IRB Chair conducts expedited review. Review generally takes 2 weeks.

Full-board conducts review at a convened meeting (see web for meeting dates). Review generally takes 4-6 weeks.

Headquarters level review conducted through review of the IRB minutes and/or through attendance of a representative of the Component Designated Official (CDO) at the convened meeting.

HSRRB

PI and EDO arrange for scientific review of the study.

EDO forwards protocol and scientific review to the Component Designated Oversight Office (CDOO).

CDOO conducts headquarters level review and forwards the protocol to HSRRB with a recommendation for either expedited or full-board review.

Expedited review is conducted by HSRRB staff and approved by the HSRRB chair or vice-chair. Review generally takes 5-6 weeks.

Full-board conducts review at a convened meeting (see web for meeting dates). Review generally takes 8-10 weeks.

Contact List:

CDO Oversight Office:	Caroline.Miner@tma.osd.mil
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